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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,629	12/14/2001	Curtis D. Pfeiffer	44557	5189

109 7590 12/30/2003

THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION
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EXAMINER	
LUDLOW, JAN M	

ART UNIT	PAPER NUMBER
1743	7

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Applicati n No.	Applicant(s)	
	10/018,629	PFEIFFER ET AL.	
	Examiner	Art Unit	
	Jan M. Ludlow	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P ri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9-16 and 21* is/are allowed.

6)☒ Claim(s) *1-8 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The disclosure is objected to because of the following informalities: On page 3, portions of lines 45-52 are illegible. On page 5, portions of lines 40-48 are illegible. On page 7, portions of lines 40-47 are illegible.

Appropriate correction is required.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4, 6-8, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chappell et al.

Chappell teaches a method of comparing transgenic products to control products. Samples are extracted in alcohol/water with KOH added and subjected to GC analysis. Three fractions for root, callus and leaf are used, as shown by the data in Table 4, which also identifies peak differences between the transgenic sample and control, i.e., the instant "outlier" (cols. 3-4, Example 3). Chappell further teaches that isopropanol is a suitable extraction alcohol (col. 20, lines 23-24) and that positive identification of peaks by GC/MS may be performed (col. 27, line 31).

Chappell fails to explicitly teach that the method of example 3 uses isopropanol or GC/MS.

It would have been obvious to use isopropanol as the alcohol in the method of Chappell in order to use a suitable alcohol as taught by Chappell. It would have been further obvious to use GC/MS to identify the peaks in order to make positive identification of the chemical composition of the peaks as taught by Chappell. With respect to claims 3-4, it would have been obvious to perform the method steps in any logical order in order to perform the required steps for comparison as taught in that there is no criticality to the order of sample preparation and chromatographing between the control and transgenic sample. With respect to claim 7, it would have been obvious to use a computer for data analysis in order to automate calculation as was known in the art. With respect to claim 19, it would have been obvious to use less than the total extract volume for the chromatography, e.g., in order to optimize column loading as was

known in the art. With respect to claim 20, it would have been obvious to, e.g., run duplicate samples and determine the average result in order to increase confidence in data as was known in the art.

5. Claims 5 and 18/5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chappell as applied to claims 1-4, 6-8, 18 above, and further in view of Waggle et al.

Chappell fails to teach liquid chromatography of the sterol-containing extracts.

Waggle teaches that sterols in plant extracts can be further purified by HPLC (col. 6, lines 59-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use HPLC in place of GC in the invention of Chappell in order to further separate sterols in plant extracts by an alternative form of chromatography as taught by Waggle. Note that Waggle specifically cites as suitably separated 3 of the sterols found in Table 4 of Chappell.

6. Claims 9-16, 21 are allowed.

The prior art fails to teach or suggest the method as claimed, including the production of the first, second and third fractions by the methods claimed from subject and control biological materials, chromatographing the fractions and comparing the chromatograms to determine chemically related differences.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Derwent Acc. No. 1994-107916 teaches extraction with isopropanol and water followed by liquid chromatography.

2. The declaration under 37 CFR 1.132 filed October 10, 2003 is insufficient to overcome the rejection of claims 1-8, 18-20 based upon Chappell as set forth in the last Office action because: The showing of unexpected results is not commensurate in scope with the claims. Applicant has shown a comparison for ONE biological material, whereas the instant claims are directed to biological materials in general, exemplified in the specification by hundreds of materials (e.g., pages 3-5) and reading broadly on millions upon millions of materials. Further, applicant only showed a comparison of 1:1 IPA/water, 0.1N KOH vs. 1:1 methanol/water, 0.1N KOH, whereas the instant claims do not specify concentrations AND recite in the alternative IPA/water, not requiring KOH. In summary, applicant has shown an unexpected result for extracting tobacco with 1:1 IPA/water, 0.1N KOH, whereas the instant claims are not so limited and encompass ANY biological material extracted with ANY combination of IPA and water, with or without KOH. Note further with respect to the "broad range" of materials extracted, the chromatograms show that both methanol and IPA extract a broad range of compounds, although in the exemplary tobacco sample, it does appear that IPA extracts more compounds.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml
December 24, 2003